

Notice of Allowability	Application No.	Applicant(s)	
	10/660,122	ECKER ET AL.	
	Examiner	Art Unit	
	ANGELA BERTAGNA	1637	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to the telephonic interviews held on 8/14/08 and 8/20/08.
2. ☒ The allowed claim(s) is/are 30-33 and 50-62.
3. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) ☐ All b) ☐ Some* c) ☐ None of the:
 1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: ____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
 - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
 - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date ____.
 - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date ____.

Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

- | | |
|---|--|
| <ol style="list-style-type: none"> 1. <input type="checkbox"/> Notice of References Cited (PTO-892) 2. <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) 3. <input checked="" type="checkbox"/> Information Disclosure Statements (PTO/SB/08),
Paper No./Mail Date <u>8/22/08</u> 4. <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit of Biological Material | <ol style="list-style-type: none"> 5. <input type="checkbox"/> Notice of Informal Patent Application 6. <input checked="" type="checkbox"/> Interview Summary (PTO-413),
Paper No./Mail Date <u>20080820</u> . 7. <input checked="" type="checkbox"/> Examiner's Amendment/Comment 8. <input checked="" type="checkbox"/> Examiner's Statement of Reasons for Allowance 9. <input type="checkbox"/> Other ____. |
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/GARY BENZION/
Supervisory Patent Examiner, Art Unit 1637

DETAILED ACTION

1. This Office Action is in response to the telephonic interviews held on August 14, 2008 and August 20, 2008. As discussed in the attached Interview Summary, the following examiner's amendment was suggested in the telephonic interviews in order to overcome the previously made rejections of claims 30-33 and 50-62 under 35 U.S.C. 112, first paragraph (new matter) and the rejection under 35 U.S.C. 112, second paragraph.

Also, as discussed in the attached Interview Summary, the previously made obviousness-type double patenting rejections citing US 7,108,974 and US 7,226,739 are withdrawn since Applicant filed proper terminal disclaimers over Application No. 10/156,608 (issued as 7,108,974) and Application No. 10/660,997 (issued as 7,226,739) on May 8, 2006.

No other rejections or objections are pending.

Information Disclosure Statement

2. Applicant's submission of an Information Disclosure Statement on August 22, 2008 is acknowledged. A signed copy is enclosed.

Terminal Disclaimer

3. The terminal disclaimer filed on August 21, 2008 disclaiming the terminal portion of any patent granted on this application which would extend beyond the expiration date of any patent granted on Application Serial No. 11/331,978 has been reviewed and is accepted. The terminal disclaimer has been recorded.

EXAMINER'S AMENDMENT

4. An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Chris Sappenfield on August 20, 2008.

The application has been amended as follows:

In the claims:

30. (currently amended) A method of identifying a virus comprising:

contacting nucleic acid from said virus with at least one pair of primers which hybridize to flanking sequences of said nucleic acid, wherein said flanking sequences flank a variable nucleic acid sequence of said virus;

amplifying said variable nucleic acid sequence to produce an amplification product;

determining the base composition of said amplification product by mass spectrometry, wherein said base composition identifies the number of A residues, C residues, T residues, G residues, U residues, analogues thereof and[[/or]] mass tag residues thereof in said amplification product; and

comparing said base composition of said amplification product to calculated or measured base compositions of analogous amplification products of one or more known viruses present in

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a database comprising 5 or more base compositions with the proviso that sequencing of said amplification products is not used to identify the virus.

Reasons for Allowance

5. The following is an examiner's statement of reasons for allowance: The instant claims are drawn to a method for identifying a virus in a sample using PCR amplification and mass spectroscopy. The method requires the use of a pair of amplification primers that flanks a variable region and comparison of the base composition obtained by analysis of the amplification products by mass spectroscopy to those found in a database comprising five or more known base compositions. There is no prior art that anticipates the claimed method. The declaration filed on October 6, 2006 overcomes the *prima facie* case of obviousness cited in the prior Office Action. As noted in related cases, the skepticism in the art evidenced by the Buchsbaum declaration is persuasive as a secondary consideration of non-obviousness. The skepticism of the JASON group in an internal review, as noted in point 3 of the declaration, that the project was not likely to be successful, persuasively argues that the claimed invention is not obvious.

It is further noted that the references and cited combination of art in the Information Disclosure Statement filed on August 22, 2008 have been fully reviewed and considered, but they were not found to be relevant to allowability of the instant claims based on the evidence made of record by the Declaration filed on October 6, 2006. Accordingly, the claimed invention is deemed novel and unobvious.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue

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fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Conclusion

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to ANGELA BERTAGNA whose telephone number is (571)272-8291. The examiner can normally be reached on M-F, 7:30 - 5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on 571-272-0782. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

amb

/GARY BENZION/

Supervisory Patent Examiner, Art Unit 1637